REMARKS

Claims 1, 3, 5-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonner et al., USPN 5,902,331. Claims 1, 3, 5-10, 12,14, 16-17, 21-23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Landberg et al., USPN 6,527,769. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by VandenEinde et al., USPN 5,415,639. Claims 4, 14, 16-18, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over or Bonner et al., USPN 5,902,331.

As the Examiner is well aware, the pending claims must be considered as a whole. Each and every element of the claims must be considered and considered in the context of the claim as a whole.

Applicants respectfully assert that the Examiner has improperly ignored claim elements. First, the Examiner has labeled the positively recited "electrode assembly" as being "hypothetical." Applicants respectfully request specific references to the applicable laws and rules of practice permitting an Examiner to designate claim elements as hypothetical and then ignoring them. Second, the Examiner has continued to refer to language as merely indicative of intended use. Rather, the language in question is functional language, which is explicitly permitted by the rules of practice that defines structure by what it does rather than by what it is. The language does define structure nonetheless.

Claim 1 includes "a coupling member . . . adapted to slidably engage an electrode assembly." Thus, an "electrode assembly" is an unambiguously, positively recited element of the claim. Further, the claim continues "advancement of the electrode assembly . . . causes separation of the electrode assembly from the coupling member within the vascular structure, whereby the electrode assembly may be located at a predetermined site of implant while the fixation member is expanded." Thus, the element is positively recited and its relationship to other elements is clearly defined. The preamble of the claim indicates that the claim entails a system. That system is

used for deploying electrode assemblies. One element of that system is an electrode assembly as positively recited multiple times in the quoted language.

Should the Examiner continue to maintain such a rejection, Applicants respectfully request specific reference to an applicable legal basis for designating certain claim elements as "hypothetical" and subsequently ignoring those elements. To the extent the Examiner is considering form over substance, e.g., how the "electrode assembly" is introduced in the claim, Applicants respectfully assert that MPEP 2173.02 precludes rejections on such a basis. Furthermore, claim elements cannot be ignored in forming a rejection under 35 USC 102 or 103. To the extent the language were ambiguous, and it is not in this case, then a rejection under section 112 would be proper; however, consideration with respect to the art is based upon what is recited in the claims based upon a reasonable interpretation of the language in question – not by ignoring that language.

"A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms." *"A functional limitation must be evaluated and considered just like any other limitation of the claim*, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context for which it is used." MPEP 2173.05(g) (Emphasis Added).

While the Examiner is superficially alluding to this requirement by twisting the reference's teachings into something they are not in order provide something "capable of performing" some of the recited functionality, the Examiner has not done so while either considering the claims as a whole or the references as a whole. Thus, the structure defined by the functional language in the present claims is not taught or suggested by the prior art.

For example, the expandable portion of Bonner et al. could, in the abstract, expand in a vessel and secure the catheter, but only if you were to ignore the remainder of the reference, which teaches that, that expansion serves to open the receiving lumen 79. When that lumen is in place, then the expanding member cannot in fact perform such a securing function; thus, it is structurally different than the claimed invention. In

considering claim 1 as a whole, the electrode assembly is deployable while the fixation member is expanded and securing the guiding device within a vessel. This language is not merely an "intended used" but serves to define structure; structure not taught or suggested by the art. Structure that must be capable of performing the recited functions in a vascular structure as claimed.

The Examiner asserts, "Applicant has not even stated in the claims that the coupling member is attached to the guiding member, only that it is adjacent to it. The claims only recite that the electrode lead is coupled to the coupling member." The Examiner's implication is that the claims must include such language. Applicants respectfully question the basis for such a conclusion. When construing the claims as a whole (i.e., all of the appropriate elements) and in context, those claims patentably define over the prior art. That they could be written in another form is not a basis for a rejection. In other words, whether the coupling member is defined as "adjacent" to the guiding member or "attached" to the guiding member is not relevant to the prior art of record, as that art fails to teach the claimed invention whether defined as "adjacent" or "attached."

Furthermore, Applicants fail to understand how the Examiner is able to determine that the "claims only recite that the electrode lead is coupled to the coupling member," if the electrode lead (rather, electrode assembly) is merely "hypothetical." Clearly, the Examiner has recognized that this element is present in the claims and should therefore not be ignored.

With respect to a substantive rebuttal of the rejections of record, Applicants incorporate the remarks from the previous response in their entirety. Applicants must, however, take issue with the arguments presented at page 3. Specifically, the Examiner asserts that "one could envision a 'hypothetical' lead . . . wherein the diameter (see reference number 12) of Bonner et al. is approximately the same size as the coupling member lumen and the wire 13 is of sufficient rigidity to disengage the lead by advancing the lead beyond the terminal end of the member 34."

First, what the Examiner "envisions" is not prior art; Applicants request specific reference to the law, rules of practice or case law that indicates otherwise. Second,

neither this reference nor any other reference provided teach, suggest or imply such a notion. Third, such a change would defeat the purpose of the expandable clamp, thus making such a modification legally improper. Fourth, this classically illustrates the consideration of elements and portions of references in isolation; even if such a modification were made, there is no teaching for the remainder of the claim elements in context, unless the Examiner "envisions" them into existence as well. Fifth, this illustrates a fundamental misunderstanding of the technology involved. A lead is deployed and fixated at a specific location within a patient; that is, the distal end is secured at some specific point. The proximal end is coupled with a device, such as a pacemaker. Such leads have considerable length, by definition and necessity.

The "envisioned" device would require placing the clamp at some location other than then desired location; pushing the entirety of the lead through the clamp until the proximal end is free of the clamp; then calling a surgeon (and perhaps a malpractice attorney) to extract the now free floating lead from the patient because the proximal connector of the lead is advanced beyond the clamp *within the patient's vasculature and beyond any control of the implanting physician.* To retain control of the proximal end, the clamp would be required to remain outside of the patient. This defeats the purpose of the device; in fact, eliminates it entirely and reduces the "envisioned" device to a lead with a guidewire. Obviously, the "envisioned" modification fails to form a basis form a proper basis for a rejection.

Applicant respectfully asserts that the pending claims are allowable and requests notice of the same. Should any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned.

Respectfully submitted,

Date: 10/1/04

Daniel G. Chapik
Registration No. 43,424
MEDTRONIC, INC.
Telephone: (763) 514-3066
Customer No. 25781